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NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause.

Bibliographic Source(s)

Goodman NF, Cobin RH, Ginzburg SB, Katz IA, Woode DE. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. Endocr Pract. 2011 Nov-Dec;17(Suppl 6):1-25.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: AACE Menopause Guidelines Revision Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. Endocr Pract 2006 May-Jun;12(3):315-37. [124 references]

Recommendations

Major Recommendations

The levels of evidence (1 to 4) and the recommendation grades (A to D) are defined at the end of the "Major Recommendations" field. A recommendation grade is linked to the best evidence level (BEL) available.

Executive Summary of Recommendations

Each recommendation is labeled "R" in this summary. All recommendation grades were determined by unanimous consensus of the primary writers and reviewers.

R1. Menopausal hormone therapy (MHT) may be appropriate for the relief of severe menopausal symptoms in selected postmenopausal women, on the basis of an individually determined benefit-versus-risk profile (Grade A; BEL 1).

R2. MHT may be prescribed during the perimenopause and early menopause for relief of menopausal symptoms and treatment of vulvovaginal atrophy (Grade A; BEL 1).

R3. The use of the transdermal route of estrogen administration should be considered in order to avoid the hepatic "first-pass effect," which may theoretically reduce the risk of thromboembolic disease (Grade B; BEL 3).

R4. The use of transvaginal estrogen may be considered to provide topical effects with less systemic absorption (Grade B; BEL 3).

R5. The dose of MHT may be reduced with advancing age (Grade C; BEL 3).

R6. Because of the increased risk of endometrial cancer, unopposed estrogen should not be used in women with an intact uterus (Grade D; BEL 1).

R7. Progestational agents should be used for a minimum of 10 to 14 days per month in women treated with estrogen who have an intact uterus (Grade A; BEL 1).

R8. Long-cycle therapy with use of a progestagen for 14 days every 3 months may be considered, in an effort to reduce breast exposure to progestagens, despite lack of definitive assessment of efficacy (Grade B; BEL 2).

R9. Amenorrhea may be achieved by using a low dose of a progestagen administered continuously (daily) in conjunction with estrogen. Because recent studies suggest adverse breast outcomes with continuous progesterone exposure, this form of therapy is not recommended (Grade D; BEL 2).

R10. MHT should be used in the lowest dose and for the shortest period necessary to control menopausal symptoms (Grade A; BEL 1).

R11. Therapeutic trials of nonhormonal prescription medications, including clonidine, antidepressants (selective serotonin reuptake inhibitors), and gabapentin, may be considered for the relief of menopausal symptoms in women with no specific contraindications (Grade B; BEL 2).

R12. Over-the-counter supplements should be used with caution because they are not regulated by the US Food and Drug Administration (FDA) and have the potential for interactions with drugs and for causing harm (Grade C; BEL 2).

R13. Phytoestrogens, including soy-derived isoflavonoids, result in inconsistent relief of symptoms. Because these compounds may have estrogenic effects, women with a personal or strong family history of hormone-dependent cancers (breast, uterine, or ovarian), thromboembolic events, or cardiovascular events should not use soy-based therapies (Grade D; BEL 1).

R14. Custom compounded "bioidentical hormone therapy" is not recommended (Grade D; BEL 1).

R15. FDA-approved bioidentical hormone preparations may be considered, but evidence is lacking that they are safer or more effective than traditional forms of hormone therapy (Grade C; BEL 2).

R16. MHT should be used for the prevention and treatment of osteoporosis within the context of the overall benefit-versus-risk analysis of each patient. Data from multiple randomized controlled trials (RCTs) substantiate the efficacy of estrogens in preserving bone mass and, less consistently, preventing fractures, but nonhormonal therapeutic options for bone health exist (Grade A; BEL 1).

R17. Hormone therapy for the prevention or treatment (or both) of dementia is not recommended (Grade D; BEL 1).

R18. MHT should be prescribed to women in conjunction with a thorough discussion of the possible relationship of MHT to breast cancer. Current evidence suggests that combination estrogen and progestational agent (E+P) regimens are associated with a possible higher risk of breast cancer than is therapy with estrogen alone (Grade A; BEL 1).

R19. Concordant with current FDA warnings, the task force recommends that women who are at increased risk of thromboembolic disease should not take estrogen-containing therapy (although there is evidence that transdermal estradiol may not increase this risk; see subsequent material) (Grade D; BEL 1).

R20. Women should be advised that smoking increases the risk of cardiovascular and venous thromboembolic disease when taking estrogen, and aggressive smoking cessation programs should be advised (Grade A; BEL 1).

R21. MHT is not recommended for primary or secondary prevention of cardiovascular disease (Grade D; BEL 1).

R22. Lipid profiles, smoking history, and diabetes history as well as family history should be assessed to assist in the determination of individual cardiovascular risk (Grade A; BEL 1).

R23. Women should be advised that cerebrovascular accidents occur with increased frequency in patients taking estrogen alone or E+P combination therapies in an age-dependent manner (Grade A; BEL 1).

R24. Women should be advised that there may be an increase in ovarian epithelial tumors with the use of estrogen for more than 10 years (Grade B; BEL 2).

R25. Women may be advised that several studies including the Women's Health Initiative (WHI) have demonstrated a lower risk of colon cancer in women treated with E+P combination (Grade B; BEL 2).

Definitions:

American Association of Clinical Endocrinologists Evidence Rating Based on Reference Methodology[a]

Numerical Descriptor (evidence level)[b]	Semantic Descriptor (reference method)
1	Meta-analysis of randomized controlled trials (MRCT)
1	Randomized controlled trial (RCT)
2	Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT)
2	Nonrandomized controlled trial (NRCT)
2	Prospective cohort study (PCS)
2	Retrospective case-control study (RCCS)
3	Cross-sectional study (CSS)
3	Surveillance study (registries, surveys, epidemiologic study) (SS)
3	Consecutive case series (CCS)
3	Single case reports (SCR)
4	No evidence (theory, opinion, consensus, or review) (NE)

[a]Adapted from: Mechanick et al., American Association of Clinical Endocrinologists Protocol for Standardized Production of Clinical Practice Guidelines--2010 update. Endocr Pract. 2010;16:270-283.

[b]1 = strong evidence; 2 = intermediate evidence; 3 = weak evidence; and 4 = no evidence.

Grading of Recommendations: How Different Evidence Levels Can Be Mapped to the Same Recommendation Grade[a]

Best Evidence Level	Subjective Factor Impact[b]	Two-Thirds Consensus	Mapping	Recommendation Grade
1	None	Yes	Direct	A
2	Positive	Yes	Adjust up	A
2	None	Yes	Direct	B
1	Negative	Yes	Adjust down	B
3	Positive	Yes	Adjust up	B
3	None	Yes	Direct	C
2	Negative	Yes	Adjust down	C
4	Positive	Yes	Adjust up	C
4	None	Yes	Direct	D
3	Negative	Yes	Adjust down	D
1, 2, 3, 4	Not applicable	No	Adjust down	D

[a] Starting with the left column, best evidence level (BEL), subjective factors, and consensus map to recommendation grades in the right column. When subjective factors have little or no impact ("none"), then the BEL is directly mapped to recommendation grades. When subjective factors have a strong impact, then recommendation grades may be adjusted up ("positive" impact) or down ("negative" impact). If a two-thirds consensus cannot be reached, then the recommendation grade is D. For not applicable (regardless of the presence or absence of strong subjective factors), the absence of a two-thirds consensus mandates a recommendation grade D.

[b] See "Description of Methods Used to Formulate the Recommendations" field for further information.

Adapted from: Mechanick et al., American Association of Clinical Endocrinologists Protocol for Standardized Production of Clinical Practice Guidelines--2010 update. Endocr Pract. 2010;16:270-283.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Menopause

Guideline Category

Counseling

Prevention

Risk Assessment

Treatment

Clinical Specialty

Endocrinology

Family Practice

Internal Medicine

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

Guideline Objective(s)

- To present recommendations for the use of menopausal hormone therapy (MHT) for the relief of menopausal symptoms
- To consider the possible role of MHT in the prevention of chronic disorders associated with estrogen deficiency
- To assess the benefit-versus-risk profile of MHT, including current understanding of the effects of MHT on multiple organ systems

Target Population

Selected symptomatic perimenopausal and early menopausal women

Interventions and Practices Considered

Risk Assessment/Counseling

1. Individually determined benefit-versus-risk profile
2. Consideration of absolute contraindications
3. Patient education
4. Counseling on smoking cessation
5. Lipid profiles
6. Patient and family medical histories

Treatment/Prevention

1. Hormonal therapy
    - Estrogen (for women who have had a hysterectomy)
    - Estrogen plus a progestational agent, administered continuously or sequentially (for women with a uterus)
2. Nonhormonal therapy
    - Lifestyle modifications
    - Prescription medications (clonidine, antidepressants, anticonvulsants [gabapentin])
    - Over-the-counter and herbal preparations (e.g., soy-based therapies)
3. Route of administration (oral, transdermal, transvaginal)
4. Consideration of dose and duration of treatment

Note: The following were considered but not recommended:

Continuous low-dose progestagen administered with estrogen to achieve amenorrhea
Custom compounded bioidentical hormone therapy
Use of MHT for primary or secondary prevention of cardiovascular disease or prevention or treatment of dementia

Major Outcomes Considered

Relief of menopausal symptoms
Beneficial effects associated with interventions
Adverse effects associated with interventions

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Evidence presented in these guidelines was obtained through MEDLINE searches and available references compiled by guideline chairs and task force members. For the 2011 update, PubMed was searched for articles published since the last guideline in 2006 using the search terms *menopause, estrogen, progesterone, hormone replacement therapy, breast cancer, cardiovascular disease, dementia*, and *vasomotor symptoms*. Reviews and high level references were included; opinion papers were excluded.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

American Association of Clinical Endocrinologists Evidence Rating Based on Reference Methodology[a]

Numerical Descriptor (evidence level)[b]	Semantic Descriptor (reference method)
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2	Nonrandomized controlled trial (NRCT)
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2	Retrospective case-control study (RCCS)
3	Cross-sectional study (CSS)
3	Surveillance study (registries, surveys, epidemiologic study) (SS)
3	Consecutive case series (CCS)
3	Single case reports (SCR)
4	No evidence (theory, opinion, consensus, or review) (NE)

[a]Adapted from: Mechanick et al., American Association of Clinical Endocrinologists Protocol for Standardized Production of Clinical Practice Guidelines--2010 update. Endocr Pract. 2010;16:270-283.

[b]1 = strong evidence; 2 = intermediate evidence; 3 = weak evidence; and 4 = no evidence.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

A task force convened by the American Association of Clinical Endocrinologists (AACE) reviewed all available evidence from MEDLINE searches. Conference calls and online discussion were used to evaluate the strength of evidence.

Expert opinion was used to evaluate the available scientific literature, which was graded for treatment recommendations by evidence-based medicine guidelines and then presented in specific references in the appended reference list.

Methods Used to Formulate the Recommendations

Description of Methods Used to Formulate the Recommendations

The task force followed the American Association of Clinical Endocrinologists (AACE) Protocol for Standardized Production of Clinical Practice Guidelines. The current protocol includes rating of evidence on the basis of the strength of scientific studies, as outlined in the "Rating Scheme for the Strength of the Evidence" field, with the addition of a subjective factor impact that may modify the final recommendation grade (see the "Rating Scheme for the Strength of the Recommendations" field). Subjective factors may include physician preferences, costs, risks, and regional availability of specific technologies and expertise when there is no definite clinical evidence. Therefore, recommendation grades are based on the best evidence level (BEL) available, including strong BEL (Grade A; BEL 1), intermediate BEL (Grade B; BEL 2), weak BEL (Grade C; BEL 3), or subjective factors when there is no clinical evidence, inconclusive clinical evidence, or contradictory clinical evidence (Grade D; BEL 4). When consensus statements are cited, even if based on a synthesis of evidence as in a published "evidence-based report," EL 4 is assigned, in accordance with AACE protocol.

Of note, in this document, a Grade D recommendation is used when the BEL is 4, rather than when consensus cannot be reached, inasmuch as all recommendations were approved unanimously by the task force and reviewers. The correctness of the recommendation grades and ELs was subjected to review at several points during the preparation of these guidelines.

A recommendation grade is linked to the BEL available. In addition to the EL, a recommendation grade, as described in the "Rating Scheme for the Strength of the Recommendations" field, may be cited with the reference number in the text. This format is intended to improve the ability of the readers to apply the information presented to clinical practice.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations: How Different Evidence Levels Can Be Mapped to the Same Recommendation Grade[a]

Best Evidence Level	Subjective Factor Impact[b]	Two-Thirds Consensus	Mapping	Recommendation Grade
1	None	Yes	Direct	A
2	Positive	Yes	Adjust up	A
2	None	Yes	Direct	B
1	Negative	Yes	Adjust down	B
3	Positive	Yes	Adjust up	B
3	None	Yes	Direct	C
2	Negative	Yes	Adjust down	C
4	Positive	Yes	Adjust up	C
4	None	Yes	Direct	D
3	Negative	Yes	Adjust down	D
1, 2, 3, 4	Not applicable	No	Adjust down	D

[a] Starting with the left column, best evidence level (BEL), subjective factors, and consensus map to recommendation grades in the right column. When subjective factors have little or no impact ("none"), then the BEL is directly mapped to recommendation grades. When subjective factors have a strong impact, then recommendation grades may be adjusted up ("positive" impact) or down ("negative" impact). If a two-thirds consensus cannot be reached, then the recommendation grade is D. For not applicable (regardless of the presence or absence of strong subjective factors), the absence of a two-thirds consensus mandates a recommendation grade D.

[b] See "Description of Methods Used to Formulate the Recommendations" field for further information.

Adapted from: Mechanick et al., American Association of Clinical Endocrinologists Protocol for Standardized Production of Clinical Practice Guidelines--2010 update. Endocr Pract. 2010;16:270-283.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

After the initial writing process, reviewers contributed their expertise to the document.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and appropriate management of menopause in women, providing symptom relief and reduced health risks associated with long-term estrogen deficiency

Potential Harms

Menopausal Hormone Therapy (MHT)

- MHT should be prescribed to women in conjunction with a thorough discussion of the possible relationship of MHT to breast cancer. Current evidence suggests that estrogen plus progestational agent (E+P) regimens are associated with a possible higher risk of breast cancer than is therapy with estrogen alone. Refer to the section on "Breast Cancer" in the original guideline document for further details.
- Progestational agents that have androgenic activity may adversely affect lipid profile, insulin sensitivity, and carbohydrate tolerance, whereas the use of antimineralocorticoid progestational compounds may be useful in causing natriuresis and potentially improving blood pressure.
- Estrogen therapy has been associated with an increased risk of venous thromboembolic disease within 1 to 2 years after initiation of therapy. The increased relative risk (RR) is high, but the increased absolute risk is quite small. In the Women's Health Initiative (WHI) study, the incidence of venous thromboembolic disease and pulmonary embolism was 3.5 per 1,000 person-years in the E+P treatment group, in comparison with 1.7 in the placebo group, with a hazard ratio (HR) of 2.06. The incidence was greater with increasing age, obesity, and factor V Leiden mutations. Women with a history of venous thromboembolic events (VTE) should be advised about this risk when HT is being considered. Because smoking further increases the risk, women should be counseled in smoking cessation. Although currently most authorities believe that there is an absolute contraindication to the use of estrogen in women with a previous history of thromboembolic disease or in women with thrombogenic mutations, recent evidence suggests that transdermal estrogen may be safe in those situations.
- The data suggest a possible increase in ovarian epithelial tumors with >10 years' use of estrogen only.
- In both treatment arms of the Women's Health Initiative study, cerebrovascular accidents (strokes) were more common in the treated group than in the placebo group, a difference that was statistically significant at the nominal but not at the adjusted levels. There was no increase in fatal strokes, but an increase was noted in the nonfatal category (nominal but not adjusted).

- In the Nurses' Health Study, the risk for ischemic or hemorrhagic stroke was modestly but statistically significantly increased among women taking 0.625 mg or more of conjugated equine estrogen (CEE): RR of 1.35 (95% CI, 1.08 to 1.68) for 0.625 mg/day and 1.63 (95% CI, 1.18 to 2.26) for women taking 1.25 mg/day or more.
- The side effects of progestational compounds are difficult to evaluate and will vary with the progestational agent administered. Some women experience premenstrual-tension-like symptoms, including mood swings, bloating, fluid retention, and sleep disturbance.

Other Therapy

- Side effects of antidepressants may include nausea, dry mouth, insomnia, fatigue, sexual dysfunction, and gastrointestinal disturbances.
- Side effects, including dry mouth, postural hypotension, fatigue, and constipation, often limit the use of clonidine.
- Side effects of gabapentin may include fatigue, dizziness, and peripheral edema.
- Although studies showed effectiveness of progesterone and progestins in reducing hot flashes, the associated side effects, including withdrawal bleeding and weight gain, often limit the use of these medications.
- Women should be counseled that data regarding the estrogenic effects of soy have been inconclusive; therefore, women with a personal or strong family history of hormone-dependent cancers (breast, uterine, or ovarian) or of thromboembolic or cardiovascular events should not use soy-based therapies. Some evidence has indicated that soy can stimulate estrogen-dependent breast cancer cells in vitro.
- There have been isolated case reports of uncertain significance of hepatitis and myopathy with the use of black cohosh.

Contraindications

Contraindications

The U.S. Food and Drug Administration (FDA) has recommended that menopausal hormone therapy (MHT) should generally *not* be prescribed to women with the following conditions:

- Current, past, or suspected breast cancer
- Known or suspected estrogen-sensitive malignant conditions
- Undiagnosed genital bleeding
- Untreated endometrial hyperplasia
- Previous idiopathic or current venous thromboembolism (deep vein thrombosis, pulmonary embolism)
- Active or recent arterial thromboembolic disease (angina, myocardial infarction)
- Untreated hypertension
- Active liver disease
- Known hypersensitivity to the active substances of MHT or to any of the excipients
- Porphyria cutanea tarda (absolute contraindication)

Qualifying Statements

Qualifying Statements

- American Association of Clinical Endocrinologists (AACE) Medical Guidelines for Clinical Practice are systematically developed statements to assist health-care professionals in medical decision making for specific clinical conditions but are in no way a substitute for a medical professional's independent judgment and should not be considered medical advice. Most of the content herein is based on literature reviews. In areas of uncertainty, professional judgment of the authors was applied.
- These guidelines are a working document that reflects the state of the field at the time of publication. Because rapid changes in this area are expected, periodic revisions are inevitable. The AACE encourages medical professionals to use this information in conjunction with their, and not as a replacement for, their best clinical judgment. The presented recommendations may not be appropriate in all situations. Any decision by practitioners to apply these guidelines must be made in light of local resources and individual patient circumstances.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Goodman NF, Cobin RH, Ginzburg SB, Katz IA, Woode DE. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. Endocr Pract. 2011 Nov-Dec;17(Suppl 6):1-25.

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 Nov-Dec (revised 2011 Nov-Dec)

Guideline Developer(s)

American Association of Clinical Endocrinologists - Medical Specialty Society

Source(s) of Funding

American Association of Clinical Endocrinologists (AACE)

Guideline Committee

American Association of Clinical Endocrinologists (AACE) Menopause Guidelines Revision Task Force

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Cochairpersons

Dr. Neil F. Goodman reports that he has received speaker honoraria from Bayer AG and consulting fees from Noven Pharmaceuticals, Inc. and Pfizer Inc.

Dr. Rhoda H. Cobin reports that she does not have any relevant financial relationships with any commercial interests.

Task Force Members

Dr. Samara B. Ginzburg reports that she does not have any relevant financial relationships with any commercial interests.

Dr. Ira A. Katz reports that he does not have any relevant financial relationships with any commercial interests.

Dr. Dwain E. Woode reports that he does not have any relevant financial relationships with any commercial interests.

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Dr. Pauline M. Camacho reports that she has received research grant support for her role as principal investigator from Eli Lilly and Company and Procter & Gamble and speaker honoraria from Warner Chilcott.

Dr. JoAnn E. Manson reports that she does not have any relevant financial relationships with any commercial interests.

Dr. Steven M. Petak reports that he does not have any relevant financial relationships with any commercial interests.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: AACE Menopause Guidelines Revision Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of menopause. Endocr Pract 2006 May-Jun;12(3):315-37. [124 references]

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Association of Clinical Endocrinologists (AACE) Web site .

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Avenue, Suite 200, Jacksonville, FL 32202.

Availability of Companion Documents

The following is available:

- American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines. Endocrine Practice; 2010 16:270-283. Electronic copies: Available in Portable Document Format (PDF) from the American Association of Clinical

Endocrinologists (AACE) Web site .

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Avenue, Suite 200, Jacksonville, FL 32202.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on October 28, 1999. The information was verified by the guideline developer on February 22, 2000. This NGC summary was updated by ECRI on August 10, 2006. The updated information was verified by the guideline developer on August 28, 2006. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This NGC summary was updated by ECRI Institute on April 10, 2012.

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